

Amendments to the Drawings:

The Examiner has objected to the drawings because the labels for each do not correspond with the written description of the drawings on pages 3 and 4. In response, Applicant attaches replacement drawing sheets in connection with the above-identified application containing Figures 1-18, presented as replacement drawing sheets to be substituted for the previously submitted drawing sheets. The numbering of Figures 1-18 in the attached drawing sheets has been amended to correspond to the numbering of Figures 1-18 on pages 3-4 of the application as filed. No new matter has been added by this amendment.

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 3-8, 10, and 12-14 have been cancelled.

Claims 1, 2, 11, and 16-18 are currently being amended. Support for the amendments to claims 1, 2, 11, and 16 can be found on page 6, line 20, through page 9, line 2, and in renumbered Figure 16. Support for the amendment to claims 17 and 18 can be found at page 13, beginning at line 3 and at line 13, respectively.

Claim 20 is being added. Support can be found at page 13, beginning at line 3.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1, 2, 9, 11, and 15-20 are now pending and under consideration in this application. No new matter is introduced by the amendment and its entry is respectfully requested. Applicant preserves the right to pursue canceled subject matter in a continuing application. Each of the rejections levied by the Examiner is addressed in turn below.

Claim Rejections - 35 U.S.C. § 112

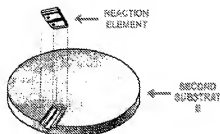
Claims 1, 2, 6-9, and 10 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter with applicant regards as invention. Specifically, the Examiner has objected to the use of the phrase “first and second substrate pieces” in claims 1 and 10. Applicant respectfully traverses this rejection, noting that claim 1 as presented fails to recite “first and second substrate pieces” and that claim 10 has been cancelled without prejudice. In view of the claims as currently amended,

Applicant believes the grounds for these rejections under § 112 to be overcome, and respectfully requests withdrawal of these rejections.

Claim Rejections - 35 U.S.C. § 102

Claims 1, 2, 6, 7, 10 and 11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bergkuist et al. (US 6,123,820; hereinafter “Bergkuist”). The Examiner alleges that Bergkuist discloses the claimed invention. Applicant disagrees. “For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference.” *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

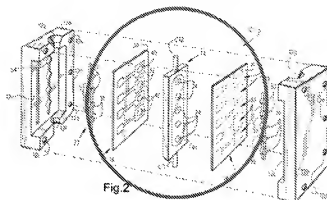
As currently amended, claimed invention recites a biomaterial measuring device and methods of making the same, wherein the device, as shown in renumbered Fig. 16, comprises the following features: (a) a biomaterial measuring device formed from two layers (a reaction element and a second substrate); (b) cavities in the second substrate that receive the reaction element and allow the introduction of biomaterial; and (c) capillaries, within the cavities of the second substrate, formed upon attachment of the reaction element to the second substrate.



As shown below, Bergkuist does not describe or disclose the claimed biomaterial measuring device formed from two layers. Rather, Bergkuist discloses a biosensor having three different layers, which are first substrate (30), sample cell (14), and second substrate (31), as shown below. Thus, Bergkuist does not teach a biomaterial measuring device assembled from just two layers. Also, a capillary is formed *within the central layer* (14) of Bergkuist, and not upon attachment of two layers, according to the presently claimed invention. Further, first and

second electrodes are formed on one surface of each of the first and second layers of Bergkuist, whereas electrodes are formed on both sides of a single layer (i.e., the reaction element) in the presently claimed device.

Fig. 2 of Bergkuist et al.



In conclusion, Bergkuist does not describe, disclose, or provide any examples of every element of the claimed invention and, thus, does not anticipate the claimed invention. Accordingly, withdrawal of this rejection under § 102 is respectfully requested.

Claim 1, 2, 6, 7, 8, 11, 15, 16, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al (US2006/0064035 A1 hereinafter “Wang”). The Wang application was filed on September 17, 2004 and published on March 23, 2006. The priority date of the present patent application is December 11, 2003, which is prior to the filing date of Wang. Thus, Wang is not prior art under § 102(e). Applicant respectfully requests that this rejection be removed.

Claim Rejections – 35 USC § 103

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bergkuist in view of Musho et al. (US 2003/0201175 A1; hereinafter “Musho”). Applicant respectfully traverses the rejection.

Prima Facie Obviousness

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007) reviewed the analysis for determining if an invention is obvious over the teachings of the prior art and affirmed the factual analysis set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). *KSR*, 127 S. Ct. at 1734 (quoting *Graham*, 383 U.S. at 17-18). MPEP § 2141, which codifies the *KSR* decision, states that: “When applying 35 U.S.C. 103...(A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) Reasonable expectation of success is the standard with which obviousness is determined.

The Examiner has not Met the Initial Burden of Supporting a Prima Facie Conclusion of Obviousness

When rejecting a claim under 35 U.S.C. §103(a), the Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness based on the above articulated standard. If the Examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. See MPEP § 2141.02.

Applicant submits that the Examiner has not met the initial burden of supporting a *prima facie* conclusion of obviousness. As stated above, Bergkuist discloses a biosensor having three different layers. Bergkuist does not teach or suggest a biosensor having just two layers or a means to make the same. Moreover, in the biosensor of Bergkuist, a capillary is formed at the central layer (14). Bergkuist does not teach or suggest a biosensor having a capillary formed by the attachment of two layers. Further, Bergkuist does not provide any motivation, or suggest the desirability, for one of skill in the art to substitute its biosensor having three different layers with biosensors having just two layers, wherein a capillary is formed by the attachment of two layers.

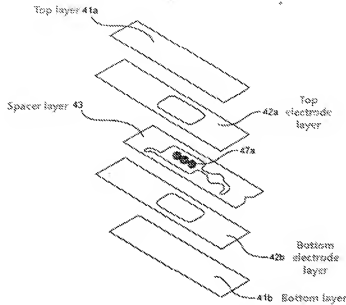
The Examiner cites Musho to allegedly cure this deficiency, although the Examiner notes at page 11, lines 7-8, item 18, of the Office Action, that “Musho fails to disclose the explicit

forming of capillaries when the two substrates are formed together.” Thus, Bergkuist and Musho, separately or in combination, fail to teach or suggest the desirability of the claimed invention or suggest any means by which it can be made with a reasonable expectation of success. Applicant respectfully requests that this rejection be removed.

Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang in view of Matzinger (US 2003/0200644A1; hereinafter “Matzinger”). As noted above, the Wang application was filed after the priority date of the present patent application. Thus, Wang is not prior art under § 103. Applicant respectfully requests that this rejection be removed.

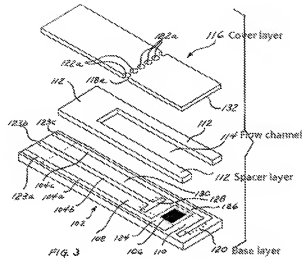
Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bergkuist in view of Matzinger. As stated above, Bergkuist discloses a biosensor having three different layers. Bergkuist does not teach or suggest a biosensor having just two layers or a means to make the same. Matzinger fails to cure the deficiencies of Bergkuist because Matzinger also discloses a biosensor having at least three different layers (including top layer 41a, middle spacer layer 43, and bottom layer 41b, as shown below) without teaching or suggesting a biosensor having just two layers.

Also, the biosensor of the Matzinger has a fluid ingress channel, corresponding to the capillary of the present invention, that is formed in the central layer (43). Matzinger does not teach or suggest the formation of a capillary by the attachment of just two layers. Thus, Bergkuist and Matzinger, separately or in combination, fail to teach or suggest the desirability of the claimed invention or suggest any means by which it can be made with a reasonable expectation of success. Applicant respectfully requests that this rejection be removed.

Fig. 9B of Matzinger

Claims 11 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Musho in view of Karinka et al. (US 2004/0067166 A1; hereinafter “Karinka”). As stated above, Musho discloses a biosensor having three different layers without teaching nor suggesting a biosensor having two different layers. Karinka fails to cure the deficiencies of Musho because Karinka also discloses a biosensor having three different layers (cover layer 116, spacer layer 112, and base layer 102). Further, the biosensor of Karinka has flow channel (114), corresponding to the capillary of the present invention, that is formed at the central layer (112). Thus, Karinka does not teach or suggest a biosensor having a capillary formed by the attachment of two layers. Thus, Musho and Karinka, separately or in combination, fail to teach or suggest the desirability of the claimed invention or suggest any means by which it can be made with a reasonable expectation of success. Applicant respectfully requests that this rejection be removed.

[Fig 3 of Karinka et al.]



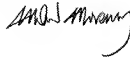
Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Musho in view of Matzinger. Again, according to the Examiner, “Musho fails to disclose the explicit forming of capillaries when the two substrates are formed together.” Also noted above, Matzinger does not teach or suggest a biosensor having just two layers or a means to make the same. Matzinger fails to cure the deficiencies of Musho. Thus, Matzinger and Musho, separately or in combination, fail to teach or suggest the desirability of the claimed invention or suggest any means by which it can be made with a reasonable expectation of success. Applicant respectfully requests that all of these rejection under § 103 be removed.

Applicant believes that the present application is now in condition for allowance.
Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application. The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect

credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,



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By _____

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